

C. Remarks

The claims are 48-61, 63-66, 73-77, 79 and 80, with claims 48 and 63 being independent. Claims 54-61 and 75-77 have been withdrawn from consideration by the Examiner as being drawn to non-elected subject matter. Claims 48 and 63 have been amended to make clear that the drug administered to the patient is one or more bisphosphonates only; claim 63 has also been amended to make more clear that the at least one bisphosphonate is administered to a human with a fractured bone. Support for these amendments can be found throughout the application as filed; no new matter has been added. Reconsideration of the present claims is respectfully requested.

Claims 48-52, 63 and 64 stand rejected under 35 U.S.C. §102(b) as being anticipated by Yates (U.S. Patent No. 5,646,134). Applicant respectfully traverses this rejection and hereby incorporates by reference all previously advanced arguments related to this rejection.

In order to anticipate a claim, each and every element as set forth in the claim must be found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814, F.2d 628 (Fed. Cir. 1987). Simply put, Yates fails to disclose each and every element of the presently pending claims. Specifically, Yates provides no teaching with regard to the use of a bisphosphonate to promote growth at a fracture site. Yates is concerned only with preventing periprosthetic bone loss by the administration of a bisphosphonate bone resorption inhibitor. Yates' mention (in its background section) of the occurrence of approximately 5 million fractures

per year can, in no way, be interpreted as a teaching of the use of bisphosphonates at the site of a bone fracture - it is a mere statement of background fact. The entire disclosure of Yates makes clear the only locus upon which the bisphosphonate is to act according to Yates:

- “. . . for the prophylaxis and treatment of failure of joint prostheses”
- col. 2, lines 48-49
- “. . . symptomatic failure of a joint prostheses or internal fixation device” - col. 2, lines 55-56
- “. . . in the periprosthetic bone area of a medical implant device” -
col. 3, lines 20-21
- “By the term ‘periprosthetic bone area’ as used herein is meant the area of bone which is in [sic] contact with the medical implant device or in the immediate proximity thereof.” - col. 3, lines 22-24
- “. . . useful for improving implant fixation, for example, for improving in growth of new bone into a metal prosthesis in joint reconstruction or orthopedic implants” - col. 4, lines 11-13

Hence, it is clear that Yates does not disclose or suggest the use of its bisphosphonate therapy at the site of a bone fracture. In direct contrast, promotion of bone growth at the site of a bone fracture is required by the present claims. Accordingly, Yates does not disclose each and every element of the present claims and cannot, therefore,

anticipate those claims. Withdrawal of the §102 rejection based upon Yates is respectfully requested.

Claims 48-53, 63, 73 and 79 stand rejected under 35 U.S.C. §102(a) as being unpatentable over Ke (U.S. Patent No. 6,352,970). Applicant respectfully traverses this rejection and hereby incorporates by reference all previously advanced arguments related to this rejection.

As noted above, in order to anticipate a claim, each and every element as set forth in the claim must be found, either expressly or inherently, in a single prior art reference. *Id.* Simply put, Ke fails to disclose each and every element of the presently pending claims. Specifically, Ke fails to disclose the use of a drug which consists only of one or more bisphosphonates. The present claims have been amended to make more clear that the bone growth effect according to the present invention is due to the action of the bisphosphonate(s) administered.

On the contrary, Ke relies upon the use of leptin or a leptin mimetic for treating low bone mass or bone fracture. Though Ke discloses a combination of leptin or a leptin mimetic and a bisphosphonate for treating bone fracture, there is no teaching or implication that the bisphosphonate itself could be used for the same purpose. In fact, Ke explicitly acknowledges that the bisphosphonate itself is not responsible for the promotion of bone growth or new bone formation at a fracture site. (“All approved therapies and clinically advanced candidates including . . . bisphosphonates . . . act to prevent bone loss by

inhibiting bone resorption, but these agents cannot restore bone mass.” Column 2, lines 14-18.)

In sum, it is clear that Ke does not disclose or suggest the use of only bisphosphonate(s) to promote bone growth at a fracture site. In direct contrast, the drug of the present invention consists only of at least one bisphosphonate. Accordingly, Ke does not disclose each and every element of the present claims and cannot, therefore, anticipate those claims. Withdrawal of the §102 rejection based upon Ke is respectfully requested.

Claims 48-50, 52, 53, 63-66, 74 and 80 stand rejected under 35 U.S.C. §102(b) as being unpatentable over Geddes (WO 93/11786). Applicant respectfully traverses this rejection and hereby incorporates by reference all previously advanced arguments related to this rejection.

As noted above, in order to anticipate a claim, each and every element as set forth in the claim must be found, either expressly or inherently, in a single prior art reference. *Id.* Simply put, Geddes fails to disclose each and every element of the presently pending claims. Specifically, Geddes fails to disclose the use of a drug which consists only of one or more bisphosphonates. The present claims have been amended to make more clear that the bone growth effect according to the present invention is due to the action of the bisphosphonate(s) administered. Furthermore, Geddes fails to disclose the promotion of bone growth at a fracture site.

On the contrary, Geddes is directed to methods of treating osteoporosis with a combination of parathyroid hormone and bisphosphonates. Geddes does not teach or

imply that bisphosphonate(s) alone could be used for the same purpose. What is more, Geddes does not teach or suggest the promotion of bone growth at a fracture site. Geddes' disclosure of the administration of a bisphosphonate to a subject with a history of atraumatic fractures is not the same as a teaching (or suggestion) of administration to a subject with a bone fracture. Accordingly, the Examiner's allegations that the method steps are the same is unfounded. The population of patients to be treated according to the presently pending claims would be those who have a bone fracture. Geddes treats no such patient.

Hence, it is clear that Geddes does not disclose or suggest the use of bisphosphonate(s) alone or the use of its combination bisphosphonate/parathyroid hormone therapy at the site of a bone fracture. In direct contrast, promotion of bone growth at the site of a bone fracture with a drug consisting of at least one bisphosphonate is required by the present claims. Accordingly, Geddes does not disclose each and every element of the present claims and cannot, therefore, anticipate those claims. Withdrawal of the §102 rejection based upon Geddes is respectfully requested.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue of the present case is respectfully requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Elizabeth F. Holowacz/
Elizabeth F. Holowacz
Attorney for Applicant
Registration No. 42,667

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

FCBS_WS 1417010v1